

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-540-(***)
	)	
SPI PHARMA, INC., DRYTEC LTD.,	)	
ANHYDRO U.K. LTD., DRYTEC	)	<b><u>DEMAND FOR JURY TRIAL</u></b>
CONTRACT PROCESSING LTD. and	)	
ANHYDRO HOLDING A/S,	)	
	)	
Defendants.	)	

**DEFENDANT SPI PHARMA, INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS  
IN RESPONSE TO PLAINTIFF'S SECOND AMENDED COMPLAINT**

Defendant, SPI Pharma, Inc. ("SPI Pharma"), by and through the undersigned counsel requests trial by jury on all issues so triable, and Answers the corresponding paragraphs of the Second Amended Complaint ("Complaint") of Plaintiff, Roquette Freres ("Plaintiff" or "Roquette"), as follows:

**JURISDICTION AND VENUE**

1. SPI Pharma admits that the complaint, on its face, alleges a cause of action for patent infringement arising under Title 35 of the United States Code, that jurisdiction of this Court is conferred by 28 U.S.C. § 1338(a), that venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) and that it has a principal place of business in the District of Delaware. SPI Pharma denies the remaining allegations of Paragraph 1 of the Complaint and specifically denies that it has engaged in infringing activities within this District.

**BACKGROUND AND PARTIES**

2. SPI Pharma admits the allegations of Paragraph 2 of the Complaint.

3. SPI Pharma admits that U.S. Patent No. 5,573,777 (the “ ‘777 patent”), on its face, lists Plaintiff as the assignee, and that a copy of the ‘777 patent is attached to the Complaint as Exhibit A. SPI Pharma otherwise has insufficient knowledge or information upon which to form a belief as to the truth of the remaining allegations and therefore denies them.

4. SPI Pharma admits the allegations of Paragraph 4 of the Complaint.

5. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph 5 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

6. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph 6 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

7. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph 7 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

**INFRINGEMENT OF THE ‘777 PATENT**

8. SPI Pharma denies the allegations contained in Paragraph 8 of the Complaint.

9. SPI Pharma denies the allegations contained in Paragraph 9 of the Complaint.

10. SPI Pharma denies the allegations contained in Paragraph 10 of the Complaint.

11. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph 11 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

12. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph 12 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

13. SPI Pharma denies the allegations contained in Paragraph 13 of the Complaint.

14. SPI Pharma admits that it sells and has been selling its MANNOGEM™ EZ Spray Dried Mannitol product in the United States. SPI Pharma denies the remainder of the allegations contained in Paragraph 14.

15. SPI Pharma denies the allegations contained in Paragraph 15 of the Complaint.

16. SPI Pharma admits that on or about September 3, 2004, it received a letter from Plaintiff asserting a claim for infringement of the '777 patent, but otherwise denies the remaining allegations of Paragraph 16 of the Complaint.

17. SPI Pharma denies the allegations contained in Paragraph 17 of the Complaint.

#### **DEFENSES and AFFIRMATIVE DEFENSES**

SPI Pharma asserts the following defenses and affirmative defenses against the allegations made by Plaintiff in the Complaint. SPI Pharma hereby reserves the right to amend its Answer and plead any additional defenses and/or counterclaims that become available or known as this action proceeds, including, but not limited to, those defenses that become known to SPI Pharma through discovery.

**First Defense**

18. SPI Pharma does not infringe any valid claim of the '777 patent, nor does SPI Pharma contribute to or induce infringement of any valid claim of the '777 patent.

**Second (Affirmative) Defense**

19. The '777 patent is invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112.

**Third (Affirmative) Defense**

20. Plaintiff's claims are barred, in whole or part, by laches.

**Fourth (Affirmative) Defense**

21. Plaintiff's claims are barred, in whole or part, by equitable estoppel.

**COUNTERCLAIMS**

For its counterclaims against Plaintiff, SPI Pharma alleges as follows:

**Nature of the Counterclaim**

22. The counterclaims herein are made under 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment of invalidity and non-infringement of the '777 patent.

23. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331 and 1338 in that the actions arise under the Patent Laws of the United States, Title 35, United States Code. Venue is proper under 28 U.S.C. § 1391 and Plaintiff has submitted itself to the jurisdiction of this Court.

24. Plaintiff and Counterclaim-Defendant Roquette is a corporation formed under the laws of France with its principal place of business at 62080 Lestrem, Cedex, France.

25. Defendant and Counterclaim-Plaintiff SPI Pharma is a Delaware corporation with its principal place of business at 321 Cherry Lane, New Castle, Delaware.

26. An actual and justiciable controversy exists between Plaintiff and SPI Pharma concerning the invalidity and non-infringement of the '777 patent.

**First Counterclaim**

27. The claims of the '777 patent are invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112.

**Second Counterclaim**

28. SPI Pharma does not infringe any valid claim of the '777 patent, nor does SPI Pharma contribute to or induce infringement of any valid claim of the '777 patent.

WHEREFORE, Defendant and Counterclaim-Plaintiff SPI Pharma asks that the Court enter an Order against Plaintiff and Counterclaim-Defendant Roquette as follows:

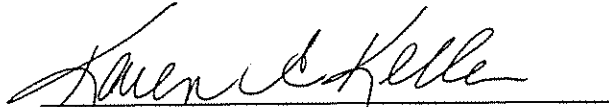
- i. That the Complaint be dismissed with prejudice, that Roquette take nothing by way of its Complaint and that SPI Pharma be awarded judgment in its favor on the claims in Roquette's Complaint;
- ii. That the Court declare, adjudge and decree that the claims of the '777 patent are invalid;
- iii. That the Court declare, adjudge and decree that SPI Pharma has not infringed and does not infringe any valid claim of the '777 patent;
- iv. That the Court declare this to be an exceptional case under 35 U.S.C. § 285 and award SPI Pharma its costs, disbursements and reasonable attorneys' fees incurred in this action;

- v. That the Court award such other and further relief as the Court may deem just and proper under the circumstances.

**JURY TRIAL DEMAND**

30. Defendant SPI Pharma demands a trial by jury on all issues so triable.

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP



John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
The Brandywine Building  
1000 West Street, 17th Floor  
Wilmington, Delaware 19801  
(302) 571-6600  
kkeller@ycst.com

*Attorneys for SPI Pharma, Inc.*

OF COUNSEL:

Brian P. Murphy, Esq.  
Daniel P. Murphy, Esq.  
Oren D. Langer, Esq.  
Morgan, Lewis & Bockius LLP  
101 Park Avenue  
New York, New York 10178  
(212) 309-6000

Dated: July 13, 2007

**CERTIFICATE OF SERVICE**

I, Karen E. Keller, hereby certify that on July 13, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Mary B. Graham, Esquire  
Julia Heaney, Esquire  
Morris, Nichols, Arsht & Tunnell LLP  
1201 North Market Street  
Wilmington, DE 19801

I further certify that on July 13, 2007, I caused a copy of the foregoing document to be served by hand delivery and e-mail on the above-listed counsel of record and on the following in the manner indicated:

**BY E-MAIL**

Douglas V. Rigler, Esquire  
Young & Thompson  
745 South 23<sup>rd</sup> Street, Suite 200  
Arlington, VA 22202

YOUNG CONAWAY STARGATT & TAYLOR, LLP

*/s/ Karen E. Keller*

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John W. Shaw (No. 3362)  
Andrew A. Lundgren (No. 4429)  
Jeffrey T. Castellano (No. 4837)  
Karen E. Keller (No. 4489)  
The Brandywine Building  
1000 West Street, 17th Floor  
Wilmington, Delaware 19801  
(302) 571-6600  
kkeller@ycst.com

*Attorneys for SPI Pharma, Inc. and Drytec Ltd.*